Alert for Healthcare Professionals

Duloxetine hydrochloride (marketed as Cymbalta)

FDA Alert [05/2005]: Suicidality in Pediatric Patients

FDA has concluded that suicidal thinking or behavior may increase in pediatric patients treated with antidepressants, especially early in treatment. Increases in suicidal thinking or behavior due to drug can be expected in about 1 out of 50 treated pediatric patients. All patients being treated with antidepressants should be observed closely for clinical worsening and suicidality especially during the first few months of therapy and when the dose is modified. Note that, although Cymbalta is prescribed for pediatric patients, it has not been approved by FDA for use in pediatric patients.

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

To report any unexpected adverse or serious events associated with the use of Cymbalta, please contact the FDA MedWatch program at 1-800-FDA-1088 or http://www.fda.gov/medwatch/report/hcp.htm

Recommendations

All pediatric patients being treated with antidepressants for any indication should be observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. Such observation would generally include at least weekly face-to-face contact with patients or their family members or caregivers during the first 4 weeks of treatment, then every other week visits for the next 4 weeks, then at 12 weeks, and as clinically indicated beyond 12 weeks. Additional contact by telephone may be appropriate between face-to-face visits.

Adults with major depressive disorder (MDD), or co-morbid depression in the setting of other psychiatric illness, being treated with antidepressants should be observed similarly for clinical worsening and suicidality, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

Data Summary

Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric

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disorders (total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4 percent, twice the placebo risk of 2 percent. No suicides occurred in these trials. Spontaneous postmarketing reports of suicide-related events associated with the use of SSRIs, including suicidal ideation, suicide attempt, self-mutilation, and completed suicide have been received. Because these events may also be related to underlying psychiatric illness, definitive evaluation of the effects of SSRIs on suicide-related events from postmarketing reports alone is not possible, and the data from controlled clinical trials are more informative.